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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

MAILED

Application Number: 09/802,546 Filing Date: March 09, 2001 Appellant(s): WHITSON, DEBI

OCT 0 5 2007

GROUP 3600

Matthew Harlow, Reg. No. 52, 994 For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/14/07 appealing from the Office action mailed 2/28/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

Claims 1-2, 4-7,9-11,13-14,17-21 are pending and stand finally rejected. However, this appeal involves only claims 1, 4, 6, 18, and 20.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,151,581	KRAFTSON et al.	11-2000
5,496,175	OYAMA et al	03-1996
2005/0187794	KIMAK	08-2005

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(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 1,4-6,9,11,13-14, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable Kimak (USPAP 2005/0187794 A1) over Kraftson et al (USPN 6,151,581-hereinafter Kraftson).
- [claim 1] Kimak discloses a process of forming an electronic medical record, the method comprising of the steps of:
- c) arranging the data stream of patient data into a defined data structure simulating the protocol structure from a party having authorization to export data to the patient's patient specific medical record; (par. 47-48, par. 64-65, par. 70-71; Figure 3) See Also par. 66-67
- d) sending the formatted data to an assigned location for importing into the patient's patient-specific medical record, wherein the electronic medical record contains specific information regarding the patient's health (par. 66-67, par. 70)

Kimak further discloses obtaining patient information from disparate sources (par. 68,71) but does not expressly disclose that the data is obtained by providing the patient with a machine-readable questionnaire concerning the patient's health.

Kraftson discloses:

- a) providing the patient with a machine-readable card including a questionnaire concerning the patient's medical history, environment, symptoms, or other pertinent information for answering by the patient; (Figure 2A-2C; 3A-3C; col. 5, line 65-col. 6, line 3, lines 41-52; col. 11, lines 43-58; col. 14, lines 28-67)
- b) interfacing a machine readable questionnaire card with a scanning type machine to convert the patient's written answers to a data stream; (col. 5, lines 1-6; col. 6, lines 3-10; Figure 4; col. 14, lines 31-35)

Claim 1 further recites providing the patient with a machine-readable card including a questionnaire.

Kraftson discloses a process further comprising providing the patient with a the machine-readable card including a questionnaire (i.e. is a paper answer sheet comprised of questions with designated areas for patient responses.) (Figures 2A-C, col. 7, lines 3-11). At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to include machine-readable card including a questionnaire. One would have been motivated to include this feature to provide a user friendly, easily accessible manner for physicians to monitor patients and their practices, without disrupting the physician's practice. (Kraftson: col. 1, lines 58-64)

[claim 4] Kimak and Kraftson teach the method of claim 1 as explained in the rejection of claim 1. Furthermore, Kraftson teaches a process wherein the machine-

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readable questionnaire includes questions concerning the systems making up the human body with designated locations for patient responses and is accomplished by a member of the clinical staff. (Col. 11, lines 43-58; Figures 2A-C; 3A-C; Figure 13—Receptionist/staff helps provide patient questionnaire.) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson for the reasons set forth in the rejection of claim 1.

[claim 5] Kimak and Kraftson teach the method of claim 1 as explained in the rejection of claim 1. Kraftson teaches a process wherein the step of interfacing the machine- readable card with the scanning type machine is accomplished by a member of the clinical staff. (col. 6, lines 1-10; col. 7, lines 3-10; col. 20, lines 5-8, lines 43-69 (e.g. Clinical staff member receives E-PDS and downloads the information patient information by connecting to the host device) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson for the reasons set forth in the rejection of claim 1.

[claims 6] Kimak discloses a process, further comprising the step of arranging the data stream into a defined format structure simulation the protocol of Health Level 7 (HL7) (par. 66)

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[claim 9] Kimak teaches a process further comprising a step of receiving the formatted data with an interface engine (par. 57-58) and sending it to the database containing the patient's electronic medical record. (par. 65-67)

[claim 11] Kimak and Kraftson teach the process of claim 4 as explained in the rejection of claim 4. Furthermore, Kraftson discloses a process wherein the machine-readable card is a paper answer sheet comprised of questions with designated areas for patient responses. (Figures 2A-C, col. 7, lines 3-11). At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to include a paper survey for the motivation provided in the rejection of claims 1 and 4.

[claim 13] Kimak discloses the method of claim 9 wherein said database is any database that accepts HL7 or ASTM messaging. (par. 34, par. 66)

[claim 14] Kimak and Kraftson disclose the method of claim 1 as explained in the rejection of claim 1. Kimak further discloses a process comprising the step of arranging the data stream into a defined format structure simulation the protocol of Health Level 7 (HL7) (par. 66) disclose receiving the data stream from the scanning type device. However, at the time of the Applicant's device, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak and Kraftson to accept the data stream from the scanning device. One would have been motivated to include this

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feature to facilitate the transfer electronic medical records from heterogeneous sources into a central registry. (Kimak: par. 3)

[claim 18] Kimak discloses a method for supplementing a medical record with medical information comprising the steps of:

- communicating the formatted data to an electronic medical record interface and adding the information to the patient's personal medical record, wherein the patient's personal medical record contains patient specific, clinical information regarding the patient's health; and (par. 47, 63-66)
- presenting the information to a physician as part of the patient's personal electronic medical record. (par. 87)

Kimak discloses obtaining patient information from disparate sources (par. 68,71) but does not expressly disclose that the data is obtained by providing the patient with a machine-readable questionnaire concerning the patient's health.

Kraftson discloses a method of obtaining patient information with information submitted by a patient, the method comprising the steps of:

- receiving from the patient a machine-readable printed form containing information about a health status of the patient; (Figures 2A-2C, 3A-3C,13; col. 5, line 65-col. 6, line 3; col. 11, lines 43-58; col. 14, lines 28-67)
- electronically scanning the printed form to convert the information to machine processable data and communicate the data to a computer; (Figures 1 and 4; col. 7, lines 3-10)

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- formatting the machine-processable data with the computer so that the data is in a form that may be communicated to an electronic medical record; (col. 7, lines 6-10;col. 9, lines 32-49; col. 13, lines 59-61)

At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to use paper machine-readable questionnaires to obtain patient information. One would have been motivated to include this feature to provide a user friendly, easily accessible manner for physicians to monitor patients and their practices, without disrupting the physician's practice. (Kraftson: col. 1, lines 58-64)

[claim 19, 21] Kimak discloses presenting the patient's electronic medical record to the physician, before the patient visits the doctor to apprise the physician of the patient's health status in the patient's absence. (par. 47,76, and 86). However, Kimak does not expressly disclose that the data is obtained from a questionnaire or that the questionnaire is mailed to a patient prior to an appointment. Kraftson discloses a method, further comprising the step of mailing the form to the patient prior to the appointment; and (col. 11, lines 9-13—Patients see doctors for the first time or on an ongoing basis to update information and may opt to fill out survey prior to any of their appts.) At the time of the Applicant's invention, it would have been to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to mail a form/questionnaire to the patient to be completed before and appointment. As suggested by Kimak, one would have been motivated to include this feature to allow the

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point of care providers to become more informed and to become part of a network is updated with medical (e.g. immunization) information. (par. 47)

[claim 20] The limitations of claim 20 are substantially similarly to claims 14 and 18. As such, claim 20 is addressed by the rejections of claims 14 and 18, and incorporated herein.

3. Claims 2, 10, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimak and Kraftson as applied to claim 1 above, and further in view of Oyama et al (USPN 5,496,175).

[claims 2 and 10] Kimak and Kraftson teaches a system/method of gathering and entering patient data into a patient database using professional staff members, (col. 7, lines 3-11) but does not expressly disclose inputting information using a microcomputer compatible keyboard. Oyama discloses a questionnaire system wherein data gathering and input of questionnaire/survey data occurs using PC's with keyboards (col. 6, lines 21-36) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method/system of Kraftson with the teaching of Oyama to allow manual input of data using a keyboard. As suggested by Oyama, one would have been motivated to include these features to increase the diversity of information that may be input into the system from the questionnaire data. (col. 1, line 55-col. 2, line 2).

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[claim 17] Kimak and Kraftson teach a process wherein the computer processor is a standard PC (col. 8, lines 60-63; col. 19, lines 21-25). Kimak and Kraftson do not expressly disclose the specifications of the computer. However, Applicant provides no explanation in the specification as to why the recited specifications (32 MB of hard drive space and a processor capable of operating at 100 MHz) provide an advantage over other processor speeds and memory requirements. Moreover, it is respectfully submitted that at the time of the applicant's invention, a hard drive with at least 32 MB of memory and a processor with at least a 100 MHz processor were well known in the computer arts. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to include a computer with at least 32 MB of hard drive memory and at least a 100 MHz processor speed in the system of Kraftson and Oyama in combination with the motivation of making the method available to medical practices and individuals with limited computer resources.

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4. Claim 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimak and Kraftson as applied to claim 1 above, and further in view of Applicant's Admission of prior art (page 8, lines 6-8 of 6/20/06 Applicant's response.)

[claim 7]

Kimak and Kraftson disclose the method of claim 1 as explained in the rejection of claim 1. Kraftson discloses a survey system and method for obtaining patient information from a questionnaire (Figure 2A-2C; col. 5, line 65-col. 6, line 3)

and converting the obtained information into a data stream (col. 6, line 5-10; col. 7, lines 3-10; Figure 4), but does not expressly disclose the specific formats that are accommodated by the system. However, it is noted that HL7, ANSI, and ASTM are well known in the art for establishing transmitting and formatting standards for data. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method/system of Kimak and Kraftson in combination to accommodate HL7, ANSI or ASTM protocol standards. One would have been motivated to include this feature to facilitate the transmission, storage, and analysis of patient data, as suggested by Kraftson (col. 2, lines 56-63).

(10) Response to Argument

(A) On page 13 of the Appeal Brief, the Appellant argues the combination of Kimak and Kraftson, the Examiner has provided no reason why a person of ordinary skill in the art would combine the teachings of Kimak and Kraftson as proposed by the Examiner.

In response, *KSR* forecloses Appellant's argument that a *specific* teaching, suggestion or motivation is required for a finding of obviousness. See *Ex parte Smith* 83 USPQ2d 1509 (citing KSR, 127 S.Ct. at 1741, 82 USPQ2d at 1396)

Moreover, in the present case, the Examiner submits that the motivations have been provided for each of the combinations which support the holding of obviousness in the rejections of claims 1,4,6,18, and 20. In each case, the motivations for the combinations are found in one or more the references themselves or would have been in the knowledge generally available to one of ordinary skill in the art.

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Claims 1,4,6,18, and 20 recite combinations which unite old elements with no change in their respective functions and which yield predictable results.

The first part of the process in this invention is to provide a patient with a questionnaire in the form of a "bubble" scan card (a paper based form with questions and designated areas for patient responses) when arriving at the medical facility. They are also given a pencil and asked to mark the "bubbles" for their answers. Next, the data from the machine readable scan card is scanned to convert the patient's written answers into an electronic data stream, as disclosed by Kraftson and explained in the rejection of independent claims 1, 18, and 20 claims.

Moreover, on page 2, lines 11-19 of the Background of the Invention, the Applicant explains that HL-7 formats have long used as a standard in the medical industry, and "govern the format for data exchange between scheduling, billing, medical records and laboratory systems." The Kimak reference provides further evidence that HL7 has long been used as a standard for electronic interchange of data. (par. 0005) As cited in the rejections of claims 1,4,6,18, and 20,

(B) Applicant further argues that Kraftson is non-analogous to the applicant's invention.

In response to applicant's argument that Kraftson is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for

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rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).

In this case, both the applicant's invention and the Kraftson reference are drawn to medical surveys, and are therefore in the same field of endeavor. In particular, both inventions are deal with "providing the patient with a machine-readable card including a questionnaire concerning the patient's medical history, environment, symptoms, or other pertinent information for answering by the patient; (Figure 2A-2C; 3A-3C; col. 5, line 65-col. 6, line 3, lines 41-52; col. 11, lines 43-58; col. 14, lines 28-67)" and "interfacing a machine readable questionnaire card with a scanning type machine to convert the patient's written answers to a data stream." Therefore, both the reference and the applicant's invention are attempting to address some of the same problems in the art, and the Kraftson reference is not seen as a non-analogous reference.

Furthermore, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

(C) On page 14 of the Appeal Brief, the Appellant argues that Kimak does not "import information into the patient's electronic record, as recited in claim 1, but rather uses electronic medical records already created by physicians."

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "import information into a patient's record...") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

It should be noted that the last positively and actively recited step in claim 1 is the "(d) sending of formatted data to an assigned location…" The claim does not recite actively recite a step of "importing information into a patient's electronic medical record." Moreover, there is nothing in the current claim language that precludes any imported data from being added to a medical record created by physicians, which Appellant argues is a distinction of the instant invention over the prior art.

Similarly, claim 20 fails to positively recite the step of "importing information into a patient's electronic medical record." Again, the last step recited in claim 20 is a communication step: "communicating the formatted data to an electronic medical record interface engine…"

In both instances, the importation of data is recited as future or intended use, a step which does not necessarily occur within the scope of the instant claim. For example in claim 1, step d) recites "sending the formatted data to an assigned location for importation into the patient's patient specific record." Similarly claim 20,

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recites, "communicating the formatted data to an electronic medical record interface engine to automatically add the information to the patient's personal electronic medical record."

Claim 18 underscores the distinction in scope and Appellant's apparent intent in not positively and actively reciting the active importation of data into the patient record. In other words, claim 18 is in fact the only independent claim in which the Appellant actively recites the <u>both</u> the communication of data and the addition of data to the patient record. ("communicating the formatted data to an electronic medical record interface and adding the information to the patient's personal medical record....")

Moreover, Kimak discloses sending or communicating the formatted data to an assigned location (e.g. an electronic medical record interface engine) and importing or adding the information into the patient's patient-specific medical record, wherein the electronic medical record contains specific information regarding the patient's health. On page 5, (par. 66-73) of Kimak, patient data from disparate sources is formatted into HL7 format then sent through a match/merge module and added to the registry database. (par. 66-70) Patient data includes patient immunization history/records (patient-specific data) and is retrievable by patient name or IPID (immunization patient identification) (par. 72, 74).

The rejection of claims 1 and 20 are proper, and should be upheld.

(D) Applicant further argues that Kimak does not receive data from users, only remote servers.

Again, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., receiving data directly from users) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Moreover, the term "users" is broad enough to encompass server owners/operators, and physicians, as well as patients.

As to appellant's assertion that there is not suggestion or motivation to modify Kimak as proposed in the Office Action to receive data directly from a patient via a machine readable questionnaire, *KSR* forecloses Appellant's argument that a *specific* teaching, suggestion or motivation is required for a finding of obviousness. See *Ex parte Smith* 83 USPQ2d 1509 (citing KSR, 127 S.Ct. at 1741, 82 USPQ2d at 1396)

Moreover, in the present case, the Examiner submits that the motivations have been provided for each of the combinations which support the holding of obviousness in the rejections of claims 1, as well as claims 4,6,18, and 20. In each case, the motivations for the combinations are found in one or more the references themselves or would have been in the knowledge generally available to one of ordinary skill in the art.

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(E) Appellant argues that Kraftson and Kimak fail to disclose how information from the patient survey forms could be arranged "into a defined data structure simulating the protocol from a party having authorization to export data to the patient's" electronic medical record.

In response to Appellant's argument that the system of Kimak cannot be combined with the system of Kraftson, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Kimak was relied upon to disclose c) arranging the data stream of patient data into a defined data structure simulating the protocol structure from a party having authorization to export data to the patient's patient specific medical record. (par. 47-48, par. 64-65, par. 70-71; Figure 3; See also Par. 66-67) Kimak discloses how patient data is obtained from disparate sources, appropriately formatted, and added the main registry.

Kimak does not expressly disclose that the data is obtained by providing the patient with a machine-readable questionnaire concerning the patient's health.

Consequently, Kraftson was relied upon to disclose a) providing the patient with a machine-readable card including a questionnaire concerning the patient's medical history, environment, symptoms, or other pertinent information for

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answering by the patient; (Figure 2A-2C; 3A-3C; col. 5, line 65-col. 6, line 3, lines 41-52; col. 11, lines 43-58; col. 14, lines 28-67). Kraftson further teaches b) interfacing a machine readable questionnaire card with a scanning type machine to convert the patient's written answers to a data stream; (col. 5, lines 1-6; col. 6, lines 3-10; Figure 4; col. 14, lines 31-35)

It was this combination of references, and a motivation cited from the Kraftson to support the holding of obviousness.

(F) Appellant argues that the Kraftson reference teaches anonymous surveys, and therefore does not disclose the Appellants limitations.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The Kraftson reference discloses the use of machine-readable questionnaires as a well-established method of obtaining data at the time of Applicant's invention. Kraftson also discloses providing the patient with a machine-readable card including a questionnaire concerning the patient's medical history, environment, symptoms, or other pertinent information for answering by the patient; (Figure 2A-2C; 3A-3C; col. 5, line 65-col. 6, line 3, lines 41-52; col. 11, lines 43-58; col. 14, lines 28-67). Kraftson further teaches interfacing a machine-readable

questionnaire card with a scanning type machine to convert the patient's written answers to a data stream (converting from printed to electronic form) (col. 5, lines 1-6; col. 6, lines 3-10; Figure 4; col. 14, lines 31-35)

Kimak stores itself includes patient specific data. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to use paper machine-readable questionnaires to obtain the patient information. One would have been motivated to include this feature to provide a user friendly, easily accessible manner for physicians to monitor patients and their practices, without disrupting the physician's practice. (Kraftson: col. 1, lines 58-64)

Furthermore, it is noted that Kraftson does not envision that the surveys be used only to gather patient satisfaction data or that there be complete patient anonymity with the surveys of the invention. (Kraftson col. 11, lines 24-58) The reference discusses patients filling out demographic and diagnostic/treatment sections of the questionnaire as requested by personnel.

(G) Appellant argues that the prior art does not teach the limitations of claim 4.

Again, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Kimak and Kraftson teach the method of claim 1 as explained in the rejection of claim 1. Furthermore, Kraftson teaches a process wherein the machine-readable questionnaire includes questions concerning the systems making up the human body with designated locations for patient responses and is accomplished by a member of the clinical staff. (Col. 11, lines 43-58; Figures 2A-C; 3A-C; Figure 13—Receptionist/staff helps provide patient questionnaire.) Kraftson further discloses in sections that the patient completes sections survey sections including diagnostic and treatment sections (i.e. questions *concerning* systems making up the human body).

(H) Appellant argues that the reference fails to disclose the limitations of claim 6, because of the "anonymity requirements" of Kraftson.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The data within the Kimak reference itself is patient specific and includes patient identifiers. (Figure 3; par. 74) As such, Kimak does disclose a process, further comprising the step of arranging the data stream into a defined format structure simulation the protocol of Health Level 7 (HL7) (par. 66)

The Kraftson reference discloses the use of machine-readable questionnaires as a well-established method of obtaining data at the time of Applicant's invention. Kraftson also discloses providing the patient with a machine-readable card including a questionnaire concerning the patient's medical history, environment, symptoms, or other pertinent information for answering by the patient; (Figure 2A-2C; 3A-3C; col. 5, line 65-col. 6, line 3, lines 41-52; col. 11, lines 43-58; col. 14, lines 28-67). Kraftson further teaches interfacing a machine-readable questionnaire card with a scanning type machine to convert the patient's written answers to a data stream (converting from printed to electronic form) (col. 5, lines 1-6; col. 6, lines 3-10; Figure 4; col. 14, lines 31-35)

At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to use paper machine-readable questionnaires to obtain the patient information.

One would have been motivated to include this feature to provide a user friendly, easily accessible manner for physicians to monitor patients and their practices, without disrupting the physician's practice. (Kraftson: col. 1, lines 58-64)

Furthermore, regarding appellant's assertion that the Kraftson surveys must be anonymous, it is submitted Kraftson does not envision that the surveys be used only to gather patient satisfaction data or that there be complete patient anonymity with the surveys of the invention. (Kraftson col. 11, lines 24-58). The reference

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discusses patients filling out demographic and diagnostic/treatment sections of the questionnaire as requested by personnel.

Appellant's discussion of Forrey and McDonald articles also underscores the universality of HL7 format in the medical field. Moreover, while Appellant argues that HL7 has only been used to communicate traditional laboratory, it is noted that the current language of claims fails 1 and 6 fails to distinguish Appellants use in the instant invention from the traditional well-known use of HL7 or the use described in the applied prior art. In other words, the type of data captured, converted and communicated in claim 6 is "patient's medical history, environment, symptoms, or other pertinent information." Traditional laboratory test data would address at least one the required categories of medical information.(e.g. medical history, environment (e.g., high/low electrolytes; dehydration; blood lead levels); other pertinent medical information).

(I) Appellant argues that the prior art does not disclose the limitations of claim 18, namely the use of forms to collect patient information and presenting the information to a physician as part of a patient's medical record.

Kimak discloses sending or communicating the formatted data to an assigned location (e.g. an electronic medical record interface engine) and importing or adding the information into the patient's patient-specific medical record, wherein the electronic medical record contains specific information regarding the patient's health. On page 5,

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par. 66-73 of Kimak, patient data from disparate sources is formatted into HL7 format then sent through a match/merge module and added to the registry database. (par. 66-70) Patient data includes patient immunization history/records (patient-specific data) and is retrievable by patient name or IPID (immunization patient identification) (par. 72, 74). Kimak further discloses presenting the information to a physician as part of the patient's personal electronic medical record. (par. 87)

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The Kraftson reference discloses the use of machine-readable questionnaires as a well-established method of obtaining data at the time of Applicant's invention. Kraftson also discloses providing the patient with a machine-readable card including a questionnaire concerning the patient's medical history, environment, symptoms, or other pertinent information for answering by the patient; (Figure 2A-2C; 3A-3C; col. 5, line 65-col. 6, line 3, lines 41-52; col. 11, lines 43-58; col. 14, lines 28-67). Kraftson further teaches interfacing a machine-readable questionnaire card with a scanning type machine to convert the patient's written answers to a data stream (converting from printed to electronic form) (col. 5, lines 1-6; col. 6, lines 3-10; Figure 4; col. 14, lines 31-35)

Kimak stores itself includes patient specific data. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to use paper machine-readable questionnaires to obtain the patient information. One would have been motivated to include this feature to provide a user friendly, easily accessible manner for physicians to monitor patients and their practices, without disrupting the physician's practice. (Kraftson: col. 1, lines 58-64)

Regarding appellant's assertion that the Kraftson surveys must be anonymous, it is noted Kraftson does not envision that the surveys be used only to gather patient satisfaction data or that there be complete patient anonymity with the surveys of the invention. (Kraftson col. 11, lines 24-58). The reference discusses patients filling out demographic and diagnostic/treatment sections of the questionnaire as requested by personnel.

(J) Appellant argues that Kimak and Kraftson do not teach the limitations of claim 20.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Kimak discloses a process, further comprising the step of arranging the data stream into a defined format structure simulation the protocol of Health Level 7 (HL7) (par. 66) (The data within the Kimak reference itself is patient specific and includes patient identifiers. (Figure 3; par. 74))

The Kraftson reference discloses the use of machine-readable questionnaires as a well-established method of obtaining data at the time of Applicant's invention. Kraftson also discloses providing the patient with a machine-readable card including a questionnaire concerning the patient's medical history, environment, symptoms, or other pertinent information for answering by the patient; (Figure 2A-2C; 3A-3C; col. 5, line 65-col. 6, line 3, lines 41-52; col. 11, lines 43-58; col. 14, lines 28-67). Kraftson further teaches interfacing a machine-readable questionnaire card with a scanning type machine to convert the patient's written answers to a data stream (converting from printed to electronic form) (col. 5, lines 1-6; col. 6, lines 3-10; Figure 4; col. 14, lines 31-35)

At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to use paper machine-readable questionnaires to obtain the patient information.

One would have been motivated to include this feature to provide a user friendly, easily accessible manner for physicians to monitor patients and their practices, without disrupting the physician's practice. (Kraftson: col. 1, lines 58-64)

Regarding appellant's assertion that the Kraftson surveys must be anonymous, it is noted Kraftson does not envision that the surveys be used only to gather patient satisfaction data or that there be complete patient anonymity with the surveys of the invention. (Kraftson col. 11, lines 24-58). The reference discusses patients filling out demographic and diagnostic/treatment sections of the questionnaire as requested by personnel.

(K) Appellant argues that Kimak and Kraftson does not teach or suggest receiving from the patient, prior to a visit with a physician, aform filled out by the patient..."

As per the recitation of "receiving from the patient, prior to a visit with a physician, aform filled out by the patient...", it is noted that the current language of the claim ("prior to a visit with a physician") does not require that the patient is a first time patient.

Kimak discloses presenting the patient's electronic medical record to the physician, before the patient visits the doctor to apprise the physician of the patient's health status in the patient's absence. (par. 47,76, and 86). However, Kimak does not expressly disclose that the data is obtained from a questionnaire or that the questionnaire is mailed to a patient prior to an appointment. Kraftson discloses a method, further comprising the step of mailing the form to the patient prior to the appointment; and (col. 11, lines 9-13—Patients see doctors for the first

time or on an ongoing basis to update information and may opt to fill out survey prior to any of their appts.)

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

TECHNOLOGY CENTER 3600

Respectfully submitted,

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